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DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government

and is available for licensing and/or co-development in the U.S. in accordance with 35

U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of

federally-funded research and development. Foreign patent applications are filed on

selected inventions to extend market coverage for companies and may also be available

for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center,

National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD,

20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-

development research collaborations, and copies of the U.S. patent applications listed

below may be obtained by contacting: Attn. Invention Development and Marketing Unit,

Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail

Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email

ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be

required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

A SNP-based blood test for predicting breast cancer survival and determining treatment strategies.

Keywords: SNP Single Nucleotide Polymorphism Array Probe Breast Cancer

Description of Technology:

Metastasis is a primary cause of patient morbidity and mortality in solid tumors.

Although recent advances in genomic technologies have provided major insights into tumor etiology, there is a significant lack of knowledge regarding the factors that contribute to metastasis.

Through studying the metastatic susceptibility of tumors, researchers at NCI's Laboratory of Cancer Biology and Genetics have discovered a select panel of single nucleotide polymorphisms (SNPs) and a method for predicting breast cancer patient's survival. In this array, SNPs are analyzed from a patient's genomic DNA (gDNA); the result can be used to predict whether a patient is likely to respond to current breast cancer treatment strategies. This invention can reassure newly diagnosed patients that they have a high probability of responding to treatment and can also identify those patients that require alternative, more aggressive therapeutic strategies. Importantly, this invention has several advantages over the currently-offered gene expression-based breast cancer prognostic tests. Since this array can be completed following routine blood draw, rather than through a tumor biopsy, the samples are more stable, the process is quicker, simpler, lessinvasive, and more cost-effective than current methods.

Potential Commercial Applications:

• Identification of patients with higher susceptibility to tumor progression (i.e.,

metastasis).

• Prediction of breast cancer survival (less than 10 years, for example) using array

and methods.

• Personalization of patient treatment.

Value Proposition:

Since the array processes DNA from blood rather than tissue from a standard biopsy or

resection of a primary tumor, it is faster, simpler, more stable, more cost-efficient, and

less-invasive because gDNA is more stable than tumor mRNA.

Development Stage:

Pre-clinical (in vivo validation)

<u>Inventor(s)</u>:

Kent W. Hunter, PhD (NCI), Howard H. Yang, PhD (NCI), Maxwell P. Lee, PhD (NCI)

Intellectual Property:

HHS Reference No. E-082-2015/0-US-01

US Provisional Application 62/297,557 (HHS Reference No. E-082-2015/0-US-

01) filed February 19, 2016 entitled "SNP-Based Assay to Predict Breast Cancer

Survival".

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development

research collaborations for methods that provide significant improvements in examining

additional SNPs for improved prognostics, and to evaluate whether the SNP signature is

associated with overall cancer incidence or effective treatment strategies.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research

collaborations, and co-development opportunities should be sent to John D. Hewes,

Ph.D., email hewesj@mail.nih.gov.

Date: September 5, 2016

John D. Hewes

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute

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